REMARKS

The above amendments and these remarks are responsive to the Office action dated July 20, 2007. Claims 1–25 and 33–43 are pending in the application. Claims 1–25 and 33–43 are rejected. By way of the present amendment, claims 1, 19, 24 and 25 have been amended, claim 34 has been cancelled, and new claims 44 and 45 have been added. In view of the amendments above, and the remarks below, applicant respectfully requests reconsideration of the application under 37 C.F.R. § 1.111 and allowance of the pending claims.

Rejections under 35 USC §§ 102 and 103

Claims 1–7, 9, 14, 15, 19, 20, 33–36, and 40–43 stand rejected under 35 U.S.C. 102(e) as being anticipated by Nash et al. (US Patent No. 6,709,427). Claims 8, 10–13, 16–18, 21–25, and 37–39 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Nash et al., either alone or variously in view of Glines et al. (US Patent No. 6,716,190) or Paskar (US Patent No. 6,623,449).

As an initial matter, Applicant respectfully points out that the present Examiner, Laura C. Schell, previously cited Nash et al. against U.S. Patent Application Serial No. 10/642,348, which is a continuation-in-part of the present application. In response, Applicant made amendments similar to those made in the present amendment to overcome the rejections in view of Nash et al. Applicant submits that the current amendments should be similarly effective in distinguishing Nash et al.

Claim 1 and its Dependent Claims

Amended claim 1 recites a needle-free jet injection device that includes, amongst other structure, an end effector that is both rigid and has a blunt distal end, with the

device being adapted to eject fluid with sufficient pressure to penetrate an outer surface of an organ without penetration of the outer surface of the organ by the end effector. As discussed previously during the prosecution of the present application, a "rigid" end effector is distinct from a "malleable and/or manipulatable" end effector, which may be adapted "to form around or within anatomical structures" during use, as discussed on page 12 of the specification of the present application. In particular, in a malleable and/or manipulatable end effector, the shape of the longitudinal axis may be manipulated during use such that the end effector may be steered or guided around or within anatomical structures during some laparoscopic, thoracoscopic, or arthroscopic procedures, or during intravascular use. In contrast to a malleable and/or manipulatable end effector, a rigid end effector, as recited in amended claim 1, is sufficiently rigid to maintain the shape of its longitudinal axis during use. Furthermore, the combination of a blunt distal end and ejecting fluid with sufficient pressure to penetrate the outer surface of the organ without penetration of the outer surface of the organ by the end effector means that only the ejected fluid penetrates the outer surface of the organ.

In contrast, Nash et al. does not disclose, teach, or suggest an end effector that is both rigid and has a blunt distal end, as recited in amended claim 1. Rather, Nash et al. discloses only fluid delivery instruments that are either both rigid and pierce the tissue being treated (i.e., are not blunt) or fluid delivery instruments intended for intravascular use, which are flexible and have blunt distal ends. In particular, the rigid fluid delivery instrument 200 shown in Fig. 7 of Nash et al. does not have a blunt distal end. Instead, the rigid fluid delivery instrument 200 of Nash et al. includes a distal end that is pointed to form a piercing member (col. 23, lines 44-45) such that the instrument

may penetrate the myocardium (col. 23, lines 25-27, and shown in Fig. 7). Concurrently, the fluid delivery instruments disclosed in Nash et al. that do have a blunt distal end, such as those shown in Figs. 8 and 14, are not rigid. Instead, the fluid delivery devices 300 that are shown in Figs. 8 and 14 of Nash et al. are "flexible pressurized intravascular access delivery instrument[s]" (see col. 12, lines 49-54, col. 13 lines 17-22, and col. 28, lines 62-67). Furthermore, the flowable agent(s) delivery instrument shown 400 in Figs. 9–11 of Nash et al. does not eject fluid with sufficient pressure to penetrate an outer surface of an organ without penetration of the outer surface of the organ by the delivery instrument. Rather, the delivery instrument shown 400 of Nash et al. "is a vibratory device which is used to penetrate a portion of the epicardium 2 and then into the myocardium 3 to deliver the flowable agent(s) into the myocardium" (see col. 25, lines 7–15, and Figs. 9–11). Accordingly, Nash et al. does not disclose, teach, or suggest an end effector that is both rigid and has a blunt distal end, let alone such a device that ejects fluid with sufficient pressure to penetrate an outer surface of the organ without penetration of the outer surface of the organ by the end effector.

For at least the reasons discussed above, the cited references, either alone or in combination, do not disclose, teach or suggest a device as claimed in amended claim 1. Claims 2–18, 33 and 35–43 depend from claim 1. Claims 2–18, 33 and 35–43, each of which contains further limitations that distinguish the cited references, are thus allowable for at least the reasons stated above with respect to claim 1. Accordingly, amended claim 1 and its dependent claims patentably distinguish the cited art, and

Applicant respectfully requests that the rejections of claims 1–18, 33 and 35–43 under 35 U.S.C. §§ 102 and 103 be withdrawn.

Claim 6

Claim 6, which depends from claim 1, recites that "the pressure with which the fluid is ejected through the orifice is sufficient to cause a transmural lesion in the organ." As described at lines 2–4 on page 9 of the specification of the present application, transmural refers to fluid penetration throughout the entire wall thickness of an organ. Furthermore, the Free Online Medical Dictionary, Thesaurus and Encyclopedia defines transmural as "extending through or affecting the entire thickness of a wall of an organ or cavity" (http://medical-dictionary.thefreedictionary.com/transmural). In contrast, Nash et al. does not disclose, teach, or suggest causing a transmural lesion, let alone fluid being ejected with a pressure sufficient to do so. In contrast, column 2, line 18 of Nash et al., as cited by the Examiner, refers to "percutaneous transluminal coronary angioplasty." Applicant respectfully points out that transluminal is not transmural. Rather, as defined by the Free Online Medical Dictionary, Thesaurus and Encyclopedia, transluminal means "through or across a lumen" (http://medical-dictionary.thefreedictionary.com/transluminal). Thus, transluminal is not transmural.

For at least these additional reasons, Nash et al. does not disclose, teach or suggest a device as claimed in claim 6. Claims 7–9 depend from claim 6 and are thus allowable for at least the reasons stated above with respect to claim 6. Accordingly, claim 6 and the claims dependent therefrom patentably distinguish the cited art, and Applicant respectfully requests that the rejections of claims 6–9 under 35 U.S.C. §§ 102 and 103 be withdrawn.

Claim 9

Claim 9, which depends from claims 1 and 6, recites a "transmural lesion [that] is sufficient to prevent electrical signals from traveling through the transmural lesion." In contrast, Nash et al. does not disclose, teach, or suggest preventing electrical signals from traveling through a transmural lesion. As an initial matter, Applicant respectfully points out that Nash et al. does not disclose a transmural lesion. Furthermore, in sharp contrast to preventing electrical signals from traveling through something, col. 15, lines 38–40 of Nash et al., as cited by the Examiner, recite "an electrically conductive element that modifies or improves the contractile motion of the myocardium." Applicant respectfully points out that an electrically conductive element does not prevent electrical signals from traveling through something.

For at least this additional reason, Nash et al. does not disclose, teach or suggest a device as claimed in claim 9. Accordingly, claim 9 patentably distinguishes the cited art, and Applicant respectfully requests that the rejection of claim 9 under 35 U.S.C. § 102 be withdrawn.

Claim 19 and its Dependent Claims

Amended claim 19 recites an end effector for a needle-free injection device that (1) is rigid, (2) has a blunt distal end, and (3) is adapted to inject a fluid through an outer surface of an internal organ and into the internal organ without penetration of the outer surface of the internal organ by the end effector. In contrast, as generally discussed above, Nash et al. does not disclose, teach, or suggest an end effector that is both rigid and has a blunt distal end, let alone such an end effector that is adapted to inject a fluid through an outer surface of an internal organ and into the internal organ without

penetration of the outer surface of the internal organ by the end effector, as recited in amended claim 19.

Thus, for at least the reasons discussed above, the cited references, either alone or in combination, do not disclose, teach or suggest an end effector as claimed in amended claim 19. Claims 20–25 depend from claim 19. Claims 20–25, each of which contains further limitations that distinguish the cited references, are thus allowable for at least the reasons stated above with respect to claim 19. Accordingly, amended claim 19 and its dependent claims patentably distinguish the cited art, and Applicant respectfully requests that the rejections of claims 19–25 under 35 U.S.C. §§ 102 and 103 be withdrawn.

New Claim 44

Applicant has added new claim 44, which depends from claims 21 and 19. Support for claim 44 may be found in Figs. 1, 2, 5, 7 and 8, and generally throughout the application as filed. No new matter is added. Applicant believes new claim 44 is allowable for at least the reasons stated above.

New Claim 45

Applicant has added new independent claim 45. Support for claim 45 may be found on pages 1, 8–9 and 18 of the specification, in Figs. 1–8, and generally throughout the application as filed. No new matter is added. New claim 45 recites a needle-free jet injection device that includes, amongst other structure, a longitudinally rigid elongate member that is both rigid and has a blunt distal end, with the device being adapted to eject fluid out of at least one injection orifice with sufficient pressure to penetrate selected internal tissue while preserving functionality of the tissue and without

penetration of the selected internal tissue by the longitudinally rigid elongate member.

For at least the reasons discussed above, the cited references, either alone or in combination, do not disclose, teach or suggest a device as claimed in new claim 45. Thus, Applicant believes new claim 45 is allowable for at least the reasons stated above.

Conclusion

Applicant believes that this application is now in condition for allowance, in view of the above amendments and remarks. Accordingly, applicants respectfully request that the Examiner issue a Notice of Allowability covering the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

Respectfully submitted,

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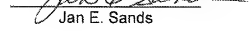

Jan E. Sands